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K051804

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SenDx Medical, Inc. ABL80 FLEX System
Traditional 510(k) SUMMARY

I. SUBMITTER INFORMATION

A. Establishment Registration: 2027541

B. Manufacturing Site: SenDx Medical, Inc.

C. Company Address: 1945 Palomar Oaks Way
Carlsbad, CA 92011

D. Date Prepared: June 2005

II. CONTACT PERSON:

A. Doreen E. Milford: Supervisor, Regulatory Affairs

B. Phone: 760-603-3401

C. Fax: 760-930-6310

D. Email: dmilford@sendx.com

III. DEVICE IDENTIFICATION

A. Trade/Proprietary Name: ABL80 FLEX System

B. Classification: Class II (21CFR862.1345)

C. Product Code: 75CHL

IV: PRODUCT DESCRIPTION:

The ABL80 FLEX System consists of a modular analyzer incorporating a user interface module with a large color touch screen interfacing to analyzer electronic and fluidic modules. The user interface module contains the analyzer CPU and all of the required electronic interfaces for external communication and data storage. The system also includes a reagent cartridge for the calibration and automatic quality control of the analyzer and sensor system. The calibration and quality control reagents are packaged in sealed foil pouches, similar to the existing ABL 77 cal pack. The analyzer and consumables incorporate "smart chip" technology for unique identification and lot specific calibration data.

The ABL80 FLEX System was developed and designed according to the design control requirements codified in 21CFR 820.30 (Design Control Process).

V. INTENDED USE:

The ABL 80 FLEX is a portable, automated system that measures pH, blood gases, electrolytes, glucose, and hematocrit in whole blood. The ABL80 FLEX system is intended for use by trained technologists, nurses, physicians and therapists. It is intended for use in a laboratory environment, near patient or point-of- care setting. The ABL80 FLEX is intended to interface with RADIANCE as a data management system.

VI. INDICATIONS FOR USE:

ABL80 FLEX is SenDx' next generation portable, cassette based analyzer targeted for decentralized settings (POC, near patient testing). The purpose of the ABL80 FLEX System is to enhance SenDx' product offering in the growing cassette based analyzer product segment. The basic concept of the ABL80 FLEX is to better address the user needs in decentralized settings. The user requirements include a desired measurement panel (blood gases, electrolytes, and glucose) in a system that has simple and infrequent steps for maintenance and replacement of consumables, an automatic Quality Control feature and a highly intuitive user interface.

VII. SUBSTANTIAL EQUIVALENCE:

The ABL 80 FLEX System is substantially equivalent to other blood gas, electrolyte, hematocrit and glucose systems used with whole blood. The same inquiries are asked of the ABL 80 FLEX System that are asked of the equivalent devices - namely do these devices accurately represent patient whole blood values for blood gases, electrolytes, hematrocrit and glucose.

The ABL80 FLEX System is similar to other currently marketed SenDx and Radiometer Medical ApS blood analysis systems such as:

510(k) Number	Device	Manufacturer
K994346	ABL77	SenDx Medical, Inc.
K980130	ABL700 Family	Radiometer Medical ApS, Copenhagen, Denmark
K050869	RADIANCE v2.5 Modification to the ABL800 FLEX	Radiometer Medical ApS, Copenhagen, Denmark

The ABL80 FLEX System is similar to the ABL77 and ABL700 Family in intended use, methods of application and principles of operation.

The methods of application involve the use by trained personnel in a central laboratory or a critical care environment. The ABL80 FLEX System is a point-of-care device and can be utilized near the patient due to the portability of the device.

With each of the listed devices and the ABL80 FLEX System the principles of operation are similar:

- Amperometric — pO2, glucose
- Potentiometric — pH, *c*Na+, *c*K+,Ca++, *c*Cl-, *p*CO2
- Conductance — Hematocrit

VIII. PERFORMANCE DATA:

The ABL™700 is the measurement standard against which performance testing has been conducted. Method comparison for pH, sodium, potassium, calcium, and chloride was against 2 ABL725 analyzers.

Method comparison for blood gases (pCO_2 and pO_2) was against target tonometry levels. Blood gas target values were calculated from certified tonometry gas mixtures traceable to NIST.

Method comparison for glucose was against serum standard per NCCLS Publication RS1-A.

Method comparison for hematocrit was against the micro-hematocrit method using centrifugation per CLSI standard H7-A3.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

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Ms. Doreen E. Milford
Supervisor, Regulatory Affairs
SenDx Medical, Inc.
1945 Palomar Oaks Way
Carlsbad, CA 92011

Re: k051804
Trade/Device Name: ABL 80 FLEX System
Regulation Number: 21 CFR 862.1120
Regulation Name: Blood gases (pH, pCO_2, and pO_2) and blood pH test system
Regulatory Class: Class II
Product Code: CHL, CEM, JFP, JGS, CGZ, CGA, JPI, JIX, JJY
Dated: September 28, 2005
Received: September 29, 2005

Dear Ms. Milford:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Alberto Gutierrez, Ph.D.
Director
Division of Chemistry and Toxicology
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Attachment A

Indications for Use

510(k) Number: K051804 **Device Name:** ABL 80 FLEX System

Intended Use:
The ABL 80 FLEX is a portable, automated system that measures pH, blood gases, electrolytes, glucose, and hematocrit in whole blood. The ABL80 FLEX system is intended for use by trained technologists, nurses, physicians and therapists. It is intended for use in a laboratory environment, near patient or point-of- care setting.

Indications for use:
These tests are only performed under a physicians order:

pH: pH is the indispensable measure of acidemia or alkalemia and is therefore an essential part of the pH/Blood gas measurement.

pO_2: The arterial oxygen tension is an indicator of the oxygen uptake in the lungs.

pCO_2: pCO_2 is a direct reflection of the adequacy of alveolar ventilation in relation to the metabolic rate.

Potassium (cK^+): The potassium level is the predominant intracellular cation. It is fundamental for correct neuromuscular activity

Sodium (cNa^+): The sodium ion is the most abundant cation in plasma. It is the foremost agent involved in maintenance of osmolality and body fluid volumes.

Calcium (cCa^{2+}): The calcium ion is the most abundant mineral element in the human body and is involved in numerous enzymatic processes, blood coagulation, cell growth, and membrane transport mechanisms as well as plays an important role in nervous impulse conduction, neuromuscular transmission, and muscular contraction and relaxation.

Chloride (cCl^-): The chloride ion is the main extracellular anion and plays an important role in maintaining electrical neutrality.

Hematocrit (Hct): The hematocrit measurement is the ratio of the volume of red blood cells in whole blood in comparison to the total volume.

Glucose ($cGlu$): The glucose measurements are used to screen for, diagnose and monitor glycemic levels in potential pre-diabetic, diabetic, hypoglycemic patients.

Prescription Use___X___ (part 21CFR 801.109) or Over-the Counter Use (Optional Format 1-2-96)

PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED.

Concurrence of CDRH, Office of In Vitro Diagnostics

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K051804